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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,908	05/13/2005	Anupam Trehan	RL1-309US	5768

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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
02/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,908	TREHAN ET AL.	
	Examiner	Art Unit	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11,12,14-24,28-32,42,43,52,54,57-60,80,81,86-90 and 94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11,12,14-24,28-32,42,43,52,54,57-60,80,81,86-90 and 94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims and Examination

Claims 1-7, 11-12, 14-24, 28-32, 42-43, 52, 54, 57-60, 80-81, and 86-90 and 94 are pending and the subject of this Office Action.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 11-12, 14-24, 28-32, 42-43, 52, 54, 57-60, 80-81, and 86-90 and 94 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent Publication No. 2003/0187074 [hereinafter referred to as "Hussain et al"].

Hussain et al, discloses as background information that biguanides, represented principally by metformin, phenformin, and buformin (Page 1, para. 3) and sulfonylureas, represented principally by glipizide, glimiperide, glyburide, glibornuride, glisoxepide, gliclazide, acetohexamide, chlorpropamide, tolazamide, and tolbutamide help in controlling or managing non-insulin dependent diabetes (Page 1, para. 5). The background information also discloses that "the administration of biguanide with sulfonylurea provides optimum glycemic control where monotherapy of each is found to be inadequate" (Page 1, para. 6; page 2, para. 15) and that "[o]ral combination products should ideally be adaptable so that release rates and profiles can be matched to physiological and chronotherapeutic specifications" (Page 1, para. 7).

At the time of the Hussain et al invention, "[t]here was no availability in clinical practice of such combinations of a pH-independent controlled release biguanide along with an immediate release glitazone or sulfonylurea, all in one physically and chemically stable dosage form for ready administration" (Page 3, para. 18) and it was believed that the same "would fill a highly desired gap in medical armamentarium" (Page 3, para. 18).

To that end, the invention of Hussain et al disclose an oral delivery system to treat diabetes in humans comprising a core with metformin, a water-insoluble polymeric carrier comprising a water-insoluble polymer and a layer comprising rosiglitazone or sulfonylurea over the core where there is a pH-independent controlled release of the metformin and an immediate release of the rosiglitazone or sulfonylurea from the layer upon administration (Page 10, Claim 17), and the core comprises a rate release modifier (Page 10, Claim 24). Additionally, the sulyonylurea layer is compressed or coated onto the core (Page 11, Claim 29), the delivery system comprises a filler, a binder, a disintegrating agent, a glidant, lubricant, or mixture thereof

(Page 11, claim 30) and the delivery system form may be a tablet which includes a coating comprising a fast-dissolving film of a water-soluble polymer and/or the tablet may be chewable, including a sweetening agent, a coloring agent, or a flavoring agent (Page 11, claims 32 and 33).

Notably, the polymers of the invention are preferably bioerodable polymers such as ethylcellulose, which may be incorporated along with the drug or applied as a coating or a combination of those two methods (Pages 4-5, para. 43). These polymer undergo bioerosion, which includes chemical and physical breakdown of a matrix comprising the polymer, and the loss of the mass from the polymer matrix causes the device to shrink with time, but the same polymers swell upon the ingress of water (Page 4, paras. 40 an 41). The polymer could comprise anywhere from about 10% to about 40% of the weight of the oral delivery system (Page 10, claim 7).

Example 5 in Hussain, et al illustrates the invention in the form of bilayered tablets of metformin and gilipizide, including the process of making the tablets, which included wet mass granulation and compression (Page 8-9, Example 5, including tables 10-12) and shows the controlled release of the biguanide, ranging from one to ten hours (Page 9, Table 11).

In light of the foregoing, it would have been prima facie obvious to one of ordinary skill in the art to combine administer a pharmaceutical solid dosage with an extended release later comprising a biguanide and an immediate release layer comprising a sulfonylurea.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

18 February 2008

Alicia Hughes

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